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**Subject:** Law 360 -Texas Agency Relaxes Guidelines For Controversial Sterilizer

### **Law360**

#### **Texas Agency Relaxes Guidelines For Controversial Sterilizer**

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**By Juan Carlos Rodriguez**

The Texas Commission on Environmental Quality said Friday the carcinogenic chemical ethylene oxide is safer than previously thought and raised the amount that can be emitted by sources that get air quality permits from the agency.

The move comes amid increasing concern about the chemical, as manufacturers face litigation from some of those exposed to it and the U.S. Environmental Protection Agency has proposed reducing the total amount of domestic emissions. The TCEQ said after an evaluation of the chemical's health risk, it is raising the safe exposure level from 1 part per billion to 2.4 parts per billion, which will serve as the upper limit on air permits issued by the agency.

"TCEQ's final ethylene oxide [effects screening level] comes during a unique period of strain on the nation's medical industry," the agency said in a statement Friday. "TCEQ's ethylene oxide cancer dose-response assessment demonstrates that this chemical, which is used to sterilize half of the approximately 40 billion medical devices used in the United States every year, poses less risk than was previously thought."

Ethylene oxide is used in antifreeze, textiles, plastics, detergents and adhesives. It is also used to sterilize equipment and plastic devices that cannot be sterilized by steam, such as medical equipment, according to the EPA.

The TCEQ framed its action in the context of how the nation is handling the coronavirus outbreak. It said that lawsuits and regulatory scrutiny have reduced the amount of the chemical available in the U.S., which has led to shortages of sterilization capability and pediatric tracheostomy tubes.

"While the agency's assessment is a purely scientific exercise and does not consider the implications for the supply of sutures, surgical kits, and other medical devices, TCEQ's final [effects screening level] for ethylene oxide may help mitigate these supply chain

risks," the agency said.

According to the American Chemistry Council, ethylene oxide is primarily produced in Texas and Louisiana. Sterigenics' sterilization plant in Illinois was closed last year amid lawsuits over exposure to the chemical. And Union Carbide is facing a proposed class action in West Virginia over alleged health effects.

The EPA classified ethylene oxide as a human carcinogen in December 2016 and came up with a risk level of 0.001 parts per billion, but that standard isn't tied to any regulation. Industry groups disputed the findings and asked the EPA to correct its conclusions, but last December the agency denied the request.

The TCEQ's report rejected the EPA's findings and methods, saying there were "several substantial scientific issues with [the EPA's] assessment."

Aside from the overall risk factor, the EPA's 2016 findings noted there was "strong evidence" that humans employed in ethylene oxide-manufacturing facilities and sterilizing facilities are at increased risk for both lymphohematopoietic and breast cancer. The TCEQ challenged that on Friday, saying evidence suggests a potential association between exposure to the chemical and increased risk of lymphohematopoietic tumors, but not breast cancer.

Environmental groups expressed concern over the TCEQ's new standard.

"The agency's determination fails to address the full threat of risk from this cancer-causing chemical. Its reasoning for weakening health protections is without scientific merit because it does not account for the many variables inherent to cancer risk, among other problems," Elena Craft, senior director for the Environmental Defense Fund's climate and health program, said Friday.

And Adrian Shelley, director of Public Citizen's Texas office, said the TCEQ's move is part of a pattern of relaxing health standards for toxic air pollution in the state.

"This spells trouble for vulnerable communities, such as those along the Houston Ship Channel," Shelley said Friday.

Both groups noted that Michael Honeycutt, the director of the TCEQ's Toxicology, Risk Assessment, and Research Division, also serves as chair of the EPA's Science Advisory Board, and said they're concerned the Texas standard could have an impact on federal regulations.

TCEQ spokesperson Andrew Keese said Friday that the new standard is scientifically rigorous and was peer-reviewed by outside scientists.

"The agency also opened up the yearslong process to public comment," Keese said. "TCEQ's toxicologists followed the latest science on its ethylene oxide standard, and the agency stands by the work."

The only regulation currently pending regarding ethylene oxide at the EPA is a proposed rule, issued in December, that sets new National Emission Standards for Hazardous Air Pollutants, or NESHAP, for ethylene oxide, and says it would reduce the total amount of ethylene oxide emitted in the U.S. by about 10 tons per year. There's no health standard associated with the rule.

--Additional reporting by Celeste Bott, Michael Phillis and Hailey Konnath. Editing by Daniel King.